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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/817,125

04/02/2004

Nabil L. Muhanna

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WOMBLE CARLYLE SANDRIDGE & RICE, PLLC

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EXAMINER

SWIGER III, JAMES L

ART UNIT

PAPER NUMBER

3775

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02/18/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/817,125	Applicant(s) MUHANNA ET AL.	
	Examiner JAMES L. SWIGER	Art Unit 3775	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 November 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11, 13, 15-22, 25 and 34-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11, 13, 16-22, 25 and 34-44 is/are rejected.
- 7) ☒ Claim(s) 15 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 4/2/2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9-11 and 37-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 recites the limitation "wherein each slot" in line 16. There is insufficient antecedent basis for this limitation in the claim. Applicant has not claimed that the ball collet has slots.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the **shaft of the centrally located protrusion** must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate

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changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 4-5, 6, 8, 13, 16, 17-22, 25 and 39 rejected under 35 U.S.C. 103(a) as being unpatentable over Tatar (US Patent 5,910,142) in view of Ferree (US Patent 6,802,844) and El-Haw et al. (US Patent 6,726,392).

Tatar discloses a device having a pedicle screw (100), and a pair of spaced-apart threaded posts (125a and 125b), that may be defined as a yoke since it harness or the components of the device. The threaded posts define a channel (122), a ball collet (Fig. 3) that is insertable into the channel, a rod (150) having first and second ends, wherein the first end is capable of being inserted into the ball collet bore (See fig. 5), a threaded cap (140) configured and dimensioned to mate with the threaded posts and that which provides a compressive force on the ball collet (see lines 14-15 of the abstract). The

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device disclosed by Tatar is also capable of being adjusted in a disassembled state, but in the assembled state (see Fig. 5) the ball collet (130) is seated in the channel (126), which may be considered concave. The rod also goes through the bore of the collet and the cap (140) is screw-coupled to the posts (125a and 125b), which have threads on the inner surfaces (124). These threads are considered integral at least with the insertion portion of the yoke portion. The yoke portion is considered fixed relative to the threaded insertion portion (upper part), which may be considered a functional limitation of the structure. Considering the entire upper portion as a yoke, the individual 'posts' of the yoke are threaded on the inner surfaces and create a concave seat (towards the bottom).

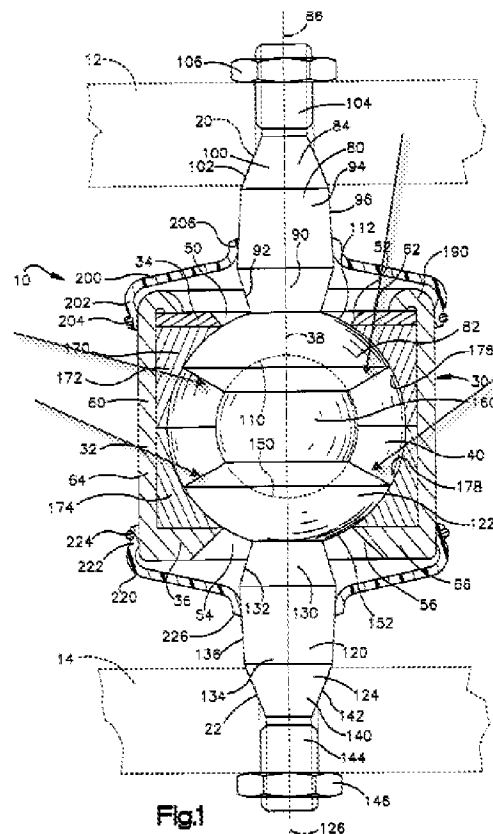
With regard to the threaded posts being fixed relative to the threaded portion, it is noted that the Tatar device comprises several parts, i.e. the yoke and insertion portion, which are rigidly secured together as a single unit when they are assembled. However, it would have been an obvious matter of design choice that the constituent parts are so combined as to constitute a unitary whole or structure, at least being fixed in a disassembled state. In re Larson, 144 USPQ 347 (CCPA 1965).

Tatar discloses the claimed invention except for at least a second end of a rod having a spherical ball member, and a device that utilizes multiple components (i.e. first, second, and third pedicle screws, first and second caps, multiple pedicle screw and rods with ends), or a ball member with a central protrusion. Ferree discloses a spinal apparatus having a rod with at least one bulbous end (Fig. 36), a device with multiple components (see Fig. 3A), or a ball member with a central protrusion (male post 83).

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These components help to secure a spinal system to vertebrae, permitting flexibility and a secure joint connection. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Tatar having at least the structure of Ferree including the spherical ball member, multiple components, and central protrusion, to secure a spinal system to vertebrae, permitting flexibility and a secure joint connection.

Tatar discloses the claimed invention except for wherein the second end of the rod has a partial hemispherical ball member having a convex inner surface facing an inboard side, and a conical surface facing an inboard side, a centrally located protrusion that is spherical, and wherein the conical surface tapers towards the spherical protrusion. El-Haw et al. disclose ball joint that is designed to allow two elongated members such as rods (for example, 94, 120, Fig. 2), articulate with respect to one another while remaining jointed. El-Haw disclose a partially hemispherical ball member (82) at an end of a rod-like member having a convex inner surface facing an inboard side (Fig. 2, 112), and an outboard side that has a conically tapering portion (see Fig. 1 below) and/towards a centrally located spherical protrusion.



It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Tatar having at least a second end of a rod having a partial hemispherical ball member having a convex inner surface facing an inboard side, and a conical surface facing an inboard side, a centrally located protrusion that is spherical, and wherein the conical surface tapers towards the spherical protrusion as taught by El-Haw et al. to have improved flexibility within the assembly while maintaining a strong joint connection.

Claims 2 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tatar (US Patent 5,910,142) in view of Ferree (US Patent 6,802,844) and El-Haw et al. (US Patent 6,726,392) as applied to claim 1 above, and further in view of Doubler et al.

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(US Publication 2005/0070899). Tatar (US Patent 5,910,142) in view of Ferree (US Patent 6,802,844) and El-Haw et al. (US Patent 6,726,392) disclose the claimed invention except for a crown having a cylindrical skirt and a radially inwardly projecting flange. Doubler et al. '899 disclose a crown with a cylindrical skirt and flange that enables the user to engage the outer spherical surface of the pedicle screw (par 0066) while this skirt rests on the inwardly projecting flange to more evenly distribute force throughout the connection (see par 0075). It would have been obvious to one having ordinary skill in the art at time the invention was made to construct the device of Tatar in view of Ferree and El-Haw et al. having at least a crown and cylindrical skirt in further view of Doubler, to better secure the device together to cause spinal fixation.

Claims 7, and 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tatar (US Patent 5,910,142) in view of Ferree (US Patent 6,802,844) and El-Haw et al. (US Patent 6,726,392) and in further view of Sgier et al. (US Pub 2005/0171538). Tatar in view of Ferree and El-Haw disclose the claimed invention except for a plurality of slots spaced about the surface of the ball collet in alternating fashion that connect with the bore. Sgier et al. disclose slots (6) that communicate with the surrounding area of the bore (par. 0019) to better fit within the cavity (par 0012). It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Tatar (US Patent 5,910,142) in view of Ferree (US Patent 6,802,844) and El-Haw et al. (US Patent 6,726,392) with the slotted collet in further view of Sgier et al. to better have the ability to grip the rod to varying degrees while in a fixed position in the spine.

Claims 34-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tatar (US Patent 5,910,142) in view of Ferree (US Patent 6,802,844) and El-Haw et al. (US Patent 6,726,392). Tatar in view of Ferree and El-Haw et al. disclose the claimed invention except for a ball collet and bore having certain dimensions. It would have been an obvious matter of design choice to construct the ball collet having certain dimensions, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. In re Rose, 105 USPQ 237 (CCPA 1955).

Claims 37-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tatar (US Patent 5,910,142) in view of Ferree (US Patent 6,802,844) and El-Haw et al. (US Patent 6,726,392) and in further view of Sgier et al. (US Pub 2005/0171538). Tatar in view of Ferree and El-Haw et al. and in further view of Sgier disclose the claimed invention except for a ball collet and bore having certain dimensions. It would have been an obvious matter of design choice to construct the ball collet having certain dimensions, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. In re Rose, 105 USPQ 237 (CCPA 1955).

Claims 40-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tatar (US Patent 5,910,142) in view of Ferree (US Patent 6,802,844) and El-Haw et al. (US Patent 6,726,392). Tatar in view of Ferree and El-Haw et al. disclose the claimed invention except for a the conically tapered surfaces being cut back to a certain degree to yield a certain amount of angular movement. It would have been obvious to one

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having ordinary skill in the art at the time the invention was made to construct the conical surfaces in such a way to yield ranges of motion of up to 40 degrees, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Allowable Subject Matter

Claim 15 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAMES L. SWIGER whose telephone number is (571)272-5557. The examiner can normally be reached on Monday through Friday, 9:00am to 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JAMES L SWIGER/
Examiner, Art Unit 3775

/Cris L. Rodriguez/
Supervisory Patent Examiner, Art Unit 3732